UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	1960.166CIP
First Named Inventor or Application Identifier	DONALD R. RICCI
Express Mail Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. [X] Fee Transmittal Form
(Submit an original, and a duplicate for fee processing)

2. [X] Specification — *Total Pages* 21

3. [X] Drawing(s) *(35 USC 113)* — *Total Sheets* 7

4. [X] Oath or Declaration — *Total Pages* 2

   a. [X] Newly executed (original or copy)
   b. [ ] Unexecuted for information purposes
   c. [ ] Copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Box 17 completed)
   [Note Box 5 below]
   i. [ ] DELETION OF INVENTOR(S)
   Signed Statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).

5. [X] Incorporation By Reference *(useable if Box 4c is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4c, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. [ ] Microfiche Computer Program *(Appendix)*

7. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
   a. [ ] Computer Readable Copy
   b. [ ] Paper Copy (identical to computer copy)
   c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. [ ] Assignment Papers (cover sheet & document(s))

9. [ ] 37 CFR 3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney

10. [ ] English Translation Document *(if applicable)*

11. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations

12. [ ] Preliminary Amendment

13. [X] Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)

14. [X] Small Entity Statement(s) [ ] Statement filed in prior application Status still proper and desired

15. [ ] Certified Copy of Priority Document(s)
(if foreign priority is claimed)

16. [ ] Other: _____

17. If a CONTINUING APPLICATION, *check appropriate box and supply the requisite information:*
[ ] Continuation [ ] Divisional [X] Continuation-in-part (CIP) of prior application No. 09/501,981, filed February 11, 2000.

18. CORRESPONDENCE ADDRESS

[X] Customer Number or Bar Code Label — 05514 (Insert Customer No. or Attach bar code label here) — or [ ] Correspondence address below

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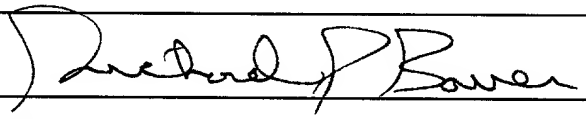
CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS (37 CFR 1.16(c))	45 -20 =	25	X $ 18.00 =	$ 450.00
	INDEPENDENT CLAIMS (37 cfr 1.16(b))	3 -3 =	0	X $ 78.00 =	$ 0.00
	MULTIPLE DEPENDENT CLAIMS (if applicable) (37 CFR 1.16(d))			$ 260.00 =	$ 0.00
				BASIC FEE (37 CFR 1.16(a))	$ 690.00
			Total of above Calculations =		$1140.00
	Reduction by 50% for filing by small entity (Note 37 CFR 1.9, 1.27, 1.28).				$ 570.00
				TOTAL =	$ 570.00

19. Small entity status
    - a. [X] A Small entity statement is enclosed
    - b. [ ] A small entity statement was filed in the prior nonprovisional application and such status is still proper and desired.
    - c. [ ] Is no longer claimed.

20. [X] A check in the amount of $ 570.00 to cover the filing fee is enclosed.

21. [ ] A check in the amount of $ _____ to cover the recordal fee is enclosed.

22. The Commissioner is hereby authorized to credit overpayments or charge the following fees to Deposit Account No. 06-1205:
    - a. [X] Fees required under 37 CFR 1.16.
    - b. [ ] Fees required under 37 CFR 1.17.
    - c. [ ] Fees required under 37 CFR 1.18.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED	
NAME	Richard P. Bauer - Reg. No. 31,588
SIGNATURE	
DATE	April 20, 2000

RPB/llp

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27 (b)) - INDEPENDENT INVENTOR	Docket No.

Serial No.	Filing Date	Patent No.	Issue Date
unknown	herewith		

Applicant/ Patentee: **Donald R. Ricci**

Invention: **STENT DELIVERY SYSTEM AND METHOD OF USE**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled above and described in:

- ☒ the specification to be filed herewith.
- ☐ the application identified above.
- ☐ the patent identified above.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ No such person, concern or organization exists.
- ☐ Each such person, concern or organization is listed below.

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27)

FULL NAME _____

ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____

ADDRESS _____

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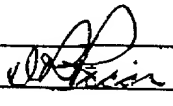
I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF INVENTOR Donald R. Ricci
SIGNATURE OF INVENTOR  DATE: April 19, 2000

NAME OF INVENTOR
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NAME OF INVENTOR
SIGNATURE OF INVENTOR DATE:

Gowlings Ref: T8465396US2
Novo RPS Ref: Challoon

FINAL VERSION

Applicant/Inventor: Donald R. Ricci

Title: Stent Delivery System and Method of Use

Jurisdiction: United States - CIP
Date: April 19, 2000

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

In one of its aspects, the present invention relates to a balloon dilation catheter. In another of its aspects, the present invention relates to a catheterization method.

BRIEF DESCRIPTION OF THE PRIOR ART

Balloon dilation catheters have been known for many years. Originally, such catheters were used in interventional techniques such as angioplasty.

In recent years, balloon dilation catheters have also been used to facilitate delivery of endovascular prosthesis' such as stents. Stents are generally known. Indeed, the term "stent" has been used interchangeably with terms such as "intraluminal vascular graft" and "expansible prosthesis". As used throughout this specification, the term "stent" is intended to have a broad meaning and encompasses any expandable prosthetic device for implantation in a body passageway (e.g., a lumen or artery).

In the past dozen years, the use of stents has attracted an increasing amount of attention due to the potential of these devices to be used, in certain cases, as an alternative to surgery. Generally, a stent is used to obtain and maintain the patency of the body passageway while maintaining the integrity of the passageway. As used in this specification, the term "body passageway" is intended to have a broad meaning and encompasses any duct (e.g., natural or iatrogenic) within the human body and can include a member selected from the group comprising: blood vessels, respiratory ducts, gastrointestinal ducts and the like.

Stent development has evolved to the point where the vast majority of currently available stents rely on controlled plastic deformation of the entire structure of the stent at the target body passageway so that only sufficient force to maintain the patency of the body passageway is applied during expansion of the stent.

Generally, in many of these systems, a stent, in association with a balloon, is delivered to the target area of the body passageway by a catheter system. Once the stent has been properly located (for example, for intravascular implantation the target area of the vessel can be filled with a contrast medium to facilitate visualization during fluoroscopy), the balloon is

expanded thereby plastically deforming the entire structure of the stent so that the latter is urged in place against the body passageway. As indicated above, the amount of force applied is at least that necessary to expand the stent (i.e., the applied force exceeds the minimum force above which the stent material will undergo plastic deformation) while maintaining the patency of the body passageway. At this point, the balloon is deflated and withdrawn within the catheter, and is subsequently removed. Ideally, the stent will remain in place and maintain the target area of the body passageway substantially free of blockage (or narrowing).

See, for example, any of the following patents:

United States patent 4,323,071 (Simpson et al.),
United States patent 4,411,055 (Simpson et al.),
United States patent 4,616,648 (Simpson),
United States patent 4,661,094 (Simpson),
United States patent 4,733,665 (Palmaz),
United States patent 4,739,762 (Palmaz),
United States patent 4,800,882 (Gianturco),
United States patent 4,907,336 (Gianturco),
United States patent 5,035,706 (Gianturco et al.),
United States patent 5,037,392 (Hillstead),
United States patent 5,041,126 (Gianturco),
United States patent 5,092,873 (Simpson et al.),
United States patent 5,102,417 (Palmaz),
United States patent 5,147,385 (Beck et al.),
United States patent 5,269,793 (Simpson),
United States patent 5,282,824 (Gianturco),
United States patent 5,316,023 (Palmaz et al.),
United States patent 5,415,634 (Glynn et al.),
United States patent 5,462,529 (Simpson et al.),
United States patent 5,755,771 (Penn et al.),

United States patent 5,980,570 (Simpson),
International patent application PCT/CA97/00151 (Penn et al.), and
International patent application PCT/CA97/00152 (Penn et al.),

for a discussion on previous stent designs and deployment systems.

Given the development of stent design, the prior art has also focussed on delivery systems for stent deployment.

One particular delivery system is taught by United States patent 4,748,982 [Horzewski et al. (Horzewski)]. Horzewski teaches a reinforced balloon dilation catheter with a slitted exchange sleeve. Essentially, the catheter comprises a tubular member having a first lumen and a second lumen. A dilation balloon is mounted on the distal end of the tubular member and is in communication with the first lumen. An opening (or notch) is disposed in the tubular member intermediate its proximal and distal ends for receiving a guidewire which travels through the second lumen and emanates out of the distal end of the tubular member. A slit is disposed on the longitudinal portion of the tubular member between the opening and an area 0.5-1 cm proximal the dilation balloon. Thus, as illustrated in Figure 1 of Horzewski, the guidewire travels partly within a lumen in the catheter (approximately 10-15 cm) and partly along the outside of the catheter (approximately 80-90 cm). This approach is also known as a "monorail" delivery system. The principal advantage of this approach is that it permits so-called "rapid exchange" of the balloon catheter with another balloon catheter. In design, the exchange is facilitated by the provision of the above-mentioned slit so that the actual exchange is done over the balloon portion only (approximately 3 cm). The principal disadvantages of this approach include: less than optimum steerability of the guidewire, difficulties in moving the guidewire with respect to the catheter, less than optimum torque control and inability to exchange the guidewire while leaving the catheter in place. The catheter illustrated by Horzewski has not gained widespread commercial popularity.

Another approach for catheterization is the so-called "over the wire" approach - this approach is discussed in many of the above-mentioned United States patents naming John P. Simpson as an inventor. In this approach, the catheter comprises a tubular member having

a first lumen and a second lumen. A dilation balloon is mounted on the distal end of the tubular member and is in communication with the first lumen. The second lumen runs through the length of the tubular member. An opening is disposed in the tubular member at its proximal end for receiving a guidewire which travels through second lumen and emanates out of the distal end of the tubular member. Thus, in the "over the wire" approach, the guidewire is encompassed by the second lumen along the entire length of the tubular member (approximately 90-105 cm). The principal advantages of the this approach include: optimum steerability, smoother movement of the guidewire with respect to the catheter (due to the coaxial relationship thereof), optimum torque control and the ability to exchange the guidewire while leaving the catheter in place. The principal is disadvantage of this approach is that exchange with another balloon catheter is relatively cumbersome (i.e., compared to the "monorail" approach discussed above.

A purported improvement over the "monorail" delivery system is described in United States patent 5,195,978 [Schiffer]. Schiffer teaches a "rapid exchange over-the-wire catheter". The purported point of novelty in Schiffer is the provision of one or more breakaway elements for progressively exposing the guidewire from the proximal end toward the distal end of the catheter. In the illustrated embodiment the breakaway element is a pull tab or tear strip. The tab strip form from a plurality of longitudinally extending generally parallel grooves form in the tubular shaft of the catheter. The Schiffer catheter is disadvantageous since it requires the physician to execute two distinct and sequential steps to achieve "rapid exchange". First, the physician must take one hand off the guidewire or the catheter and thereafter grasp and remove the pull tab or tear strip to expose the guidewire. Second, the physician must remove the catheter while the guidewire is held in position. The requirement for these two distinct and sequential steps renders the Schiffer catheter cumbersome, time consuming and impractical to use.

Accordingly, it would be desirable to have a balloon dilation catheter which combined the advantages of the above-mentioned "monorail" approach and "over the wire" approach while obviating or mitigating the disadvantages of these approaches. It would be further

advantageous if the balloon dilation catheter were readily adaptable to be used in various interventional techniques such as endovascular prosthesis delivery, angioplasty and the like.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a novel balloon dilation catheter.

It is another object of the present invention to provide a novel catheterization method.

Accordingly, in one of its aspects, the present invention provides a balloon dilation catheter comprising:

a tubular member having a proximal end and a distal end;

an inflatable balloon disposed at the distal end of the tubular member;

a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon;

a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening in the tubular member and a second opening at the distal end of the tubular member; and

a slit-forming region disposed longitudinally in the tubular member and extending along at least a portion of the tubular member, the slit-forming region causing formation of a first slit as the guidewire is separated from the second lumen.

In another of its aspects, the present invention provides a catheterization kit comprising:

a guide catheter;

a guide wire; and

a balloon dilation catheter comprising: a tubular member having a proximal end and a distal end; an inflatable balloon disposed at the distal end of the tubular member; a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon; a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening in the tubular member and a second opening at the distal end of the tubular member; and a slit-forming region disposed longitudinally in the tubular member and extending along at least a portion

of the tubular member, the slit-forming region causing formation of a first slit as the guidewire is separated from the second lumen.

In yet another of its aspects, the present invention provides a stent-mounted balloon catheter comprising:

a tubular member having a proximal end and a distal end;

an inflatable balloon disposed at the distal end of the tubular member;

a stent mounted on the inflatable balloon;

a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon;

a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening in the tubular member and a second opening at the distal end of the tubular member; and

a slit-forming region disposed longitudinally in the tubular member and extending along at least a portion of the tubular member, the slit-forming region causing formation of a first slit as the guidewire is separated from the second lumen.

Thus, the present inventor has discovered a balloon catheter which combines the advantages of the "over the wire" approach (i.e., optimum steerability, smoother movement of the guidewire with respect to the catheter (due to the coaxial relationship thereof), optimum torque control and the ability to exchange the guidewire while leaving the catheter in place) with the principal advantage of the "monorail" approach (i.e., rapid exchange of the balloon catheter with another balloon catheter while leaving the guidewire in place).

As used throughout this specification, the term "tubular member", when used in the context of the present balloon dilation catheter is intended to mean a portion of the catheter generally tubular in construction and generally representing the large majority of the overall length of the balloon dilation catheter. Typically, the tubular member will be at least about 75%, more preferably at least about 85%, most preferably at least about 95%, of the overall length of the balloon dilation catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will be described with reference to the accompanying drawings wherein like numerals designate like parts and in which:

Figure 1 illustrates a perspective view of an embodiment of the present balloon dilation catheter;

Figure 2 is a sectional view along line II-II in Figure 1;

Figure 3 is a sectional view along line III-III in Figure 1;

Figure 4 illustrates an exploded view of modified proximal end of the balloon dilation catheter illustrated in Figure 1;

Figures 5-11 illustrate steps in various catheterization techniques employing the present balloon dilation catheter;

Figure 12 illustrates a modified balloon for use in the present balloon dilation catheter;

Figure 13 illustrates a preferred embodiment of a modified tubular member for use in the present balloon dilation catheter; and

Figures 14a, 14b and 14c illustrate preferred embodiments of a modified tubular member for use in the present balloon dilation catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Thus, with reference to Figures 1-3, there is illustrated a balloon dilation catheter 100. Balloon dilation catheter 100 comprises a proximal end 105 and a distal end 110. Distal end 110 of balloon dilation catheter 100 comprises an expandable balloon 115. Proximal end 105 of balloon dilation catheter 100 comprises an single lumen Luer-type adaptor 120. Disposed between adaptor 120 and balloon 115 is a tubular member 125.

As will be apparent from Figure 1, disposed in tubular member 125 is an opening 130. Also disposed in tubular member 125 is a slit 135 which extends from opening 130 to a point in tubular member 125 just proximal balloon 115.

With particular reference to Figures 2 and 3, tubular member 125 comprises a first lumen 140 and a second lumen 150. First lumen 140 is designed to be in communication with an interior of balloon 115. The design of the interface between balloon 115 and first lumen 140 is conventional - see for example Horzewski referred to hereinabove. The construction

of tubular member 125 having opening 130, slit 135, first lumen 140 and second lumen 150 is conventional - see Horzewski referred to hereinabove.

With further reference to Figures 1-3, it will be apparent that opening 130 is designed to receive a guidewire 160. Guidewire 160 passes through second lumen 150 and out of a distal opening of tubular member 125 beyond balloon 115.

In Figure 4, there is illustrated a modification of balloon dilation catheter 100 illustrated in Figures 1-3.

Specifically, in Figure 4, Luer-type adaptor 120a is modified to contain a lumen 150a in communication with a slit 135a. As will be apparent to those of skill in the art, lumen 150a is in communication with second lumen 150 in tubular member 125. Further, slit 135a is in communication with slit 135 in tubular member 125. The modification of balloon dilation catheter 100 illustrated in Figure 4 eliminates the need for having opening 130 disposed in tubular member 125 illustrated in Figure 1.

With reference to Figures 5-9, the delivery of balloon dilation catheter 100 will be described.

As is known in the art, catheterization is normally performed to alleviate a lesion in an artery. This is shown schematically in Figures 6-9 wherein a lesion in the form of a blockage 15 obstructs an artery 20. In certain cases, it is desirable to deploy a stent at the site of the lesion to maintain the patency of artery 20 at the site of blockage 15. As shown in Figure 5, catheterization is performed through an incision in the groin area of the patient.

Thus, with reference to Figures 6 and 7, a guide catheter 25 is initially delivered into artery 20 to a region proximal of blockage 15. The proximal end of guide catheter 25 remains outside the patient.

Balloon dilation catheter 100 (Figure 1) has mounted on balloon 115 thereof a stent 30. Further, guidewire 160 in second lumen 150 such that it emanates from opening 130 and from distal end 110 of balloon dilation catheter 100. Preferably, this is achieved in a conventional manner by feeding guidewire 160 into second lumen 150 at distal end 110 of balloon dilation catheter 100 until the proximal end of guidewire 160 emanates from opening 130.

At this point, balloon dilation catheter 100 is inserted into guide catheter 25 and guidewire 160 is navigated through artery 20 to a point distally of blockage 15 (Figure 7).

Aternatively, it is possible to advance guidewire 160 to a point distally of blockage 15, after which the distal end of second lumen 150 of balloon dilation catheter 100 is passed onto the proximal end of guidewire 160. If it becomes difficult to advance guidewire 160 across blockage 15 using this technique, it is possible to advance balloon dilation catheter over the proximal end of guidewire 160 until that end exits opening 130 and the system may used in the "over-the-wire" approach described herein.

In Figure 8, there is illustrated removal of guidewire 160 while leaving balloon dilation catheter 100 in position at point proximal to blockage 15. This is an advantageous feature of the present balloon dilation catheter which is not possible with the balloon dilation catheter taught in Horzewski. Thus, guidewire 160 may simply be replaced with another guidewire by removing the original guidewire from proximal end 105 of balloon dilation catheter 100 and simply inserting a replacement guidewire (not shown) into the proximal end 105 of balloon dilation catheter 100 and through tubular member 125. Thereafter, the replacement guidewire may be navigated so that it emanates from distal end 110 of balloon dilation catheter 100. The replacement guidewire is navigated to a point distal of blockage 15.

Balloon dilation catheter 100 is then navigated over the replacement guidewire such that stent 30 is in proper position with respect to blockage 15 (Figure 8). Once the guidewire and balloon dilation catheter 100 are in the correct position, fluid is injected into first lumen 150 thereby expanding balloon 115 and stent 30 mounted thereon. Deployment of a stent in this manner is conventional and within the purview of a person skilled in the art.

In Figures 10 and 11, there is illustrated rapid exchange of balloon dilation catheter 100 while leaving guidewire 160 in place. In this case, for clarity, stent 30 is not shown on balloon 115. One of the features of the present balloon dilation catheter which distinguishes it from that in Horzewski is that guidewire 160 emanates from a proximal portion of balloon dilation catheter 100 which is always outside the body of the patient. This provides the practitioner with the "over-the-wire" approach described above. Thus, either opening 130 is located outside the body at all times during use of catheter 100 illustrated in Figure 1 or it

is necessarily emanating from the proximal end of balloon dilation catheter 100 if the modified embodiment in Figure 4 is utilized.

When it is desired to exchange balloon dilation catheter 100, the balloon dilation catheter is withdrawn from artery 20 while leaving guidewire 160 in place. As balloon dilation catheter 100 is withdrawn from the body of the patient, it may be readily separated from guidewire 160 via slit 135 along virtually the entire length of tubular member 125 - this is one of the principal advantages of the present balloon dilation catheter which, to the knowledge of the present inventors, has not been achieved with a prior balloon dilation catheter. Once distal end 110 of balloon dilation catheter 100 is withdrawn from the body, balloon 115 may be exchanged from guidewire 160 in a conventional manner.

A replacement balloon dilation catheter may then be fed over guidewire 100 and navigated into artery 20 in the area of blockage 15.

With reference to Figure 12, there is illustrated yet a further alternate embodiment to the present balloon dilation catheter. In this case, a slit 135b is provided in balloon 115b such that slit 135 is in communication with slit 135b on balloon 115b. This modification of balloon catheter 100 is particularly advantageous when the catheter is being used in an angioplasty application (i.e., without a stent mounted on balloon 115) as a pre-dilation balloon catheter allowing for enhanced rapid exchange features by facilitating withdrawal of guidewire 160 in a rapid exchange manner along virtually the entire length of tubular member 125 and balloon 115b via the combination of slits 135 and 135b. This feature is generally advantageous since it facilitates withdrawal of the balloon dilation catheter from the patient.

With reference to Figure 13, there is illustrate a preferred modification to tubular member 125 of balloon catheter 100. Specifically, a third lumen 180 is provided along substantially the entire length of tubular member 125. Disposed within third lumen 180 is a stiffening member 185 which serves to improve the "torqueability" of balloon dilation catheter. Unlike, the approach in Horzewski described above wherein a single lumen does double duty for receiving: (i) a stiffening member along most of the length of the catheter and (ii) the guidewire along a minor portion of its length, the approach shown in Figure 13 is a significant improvement over Horzewski since it maximizes both the distance over which

rapid exchange may be effected and the distance over which stiffening may be conferred to the tubular member.

With reference to Figures 14a, 14b and 14c, there is illustrated a modification to the balloon dilation catheter illustrated in Figures 1-3 and described hereinabove. In Figures 1-3 and 14a, 14b and 14c, like numerals designate like elements. As will be evident tubular member 125 has been modified to provide a weakened region A. Weaken region A comprises a thinned wall 135a (Figure 14a), 135b (Figure 14b) and 135c (Figure 14c). When it is desired to exchange balloon catheter 100, guidewire 160 is separated from tubular member 125. The separation force causes incision of thinned wall 135a (Figure 14a), 135b (Figure 14b) and 135c (Figure 14c). This causes *in situ* formation of a slit as guidewire 160 is separated from tubular member 125. The feature of *in situ* slit formation is a significant advantage over the Schiffer catheter design above since, in this embodiment of the present balloon dilation catheter, *in situ* slit formation and guidewire separation from the tubular member are achieved simultaneously in a one-step operation. Additionally, provision of thinned wall 135a (Figure 14a), 135b (Figure 14b) and 135c (Figure 14c) obviates or mitigates reduction in the integrity of tubular member 125 since a slit is not formed therein until the guidewire is removed (i.e., until a point in time after the catheter has been navigated to the target location).

While this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. For example, while the illustrated embodiments depict use of the present balloon dilation catheter in delivery of a stent, those of skill in the art will immediately appreciate that the present balloon dilation catheter may be used in percutaneous transluminal coronary angioplasty techniques. Further, as will be apparent to those of skill in the art, it is possible to combine, in a single catheter, the slit illustrated in Figures 1-3 with the weakened region illustrated in Figures 14a, 14b and/or 14c. Further, while preferred, it is not strictly necessary for the weakened region illustrated in Figures 14a, 14b and/or 14c to extend along substantially the entire length of the tubular member. Still further, the specific nature of the weakened region illustrated in Figures 14a, 14b and 14c is not particularly restricted provided that it can be readily incised as the

guidewire separated from the catheter - e.g., a perforated region or a region comprising a plurality of small, partial cuts is also useful. Various modifications of the illustrative embodiments, as well as other embodiments of the invention, will be apparent to persons skilled in the art upon reference to this description. It is therefore contemplated that the appended claims will cover any such modifications or embodiments.

All publications, patents and patent applications referred to herein are incorporated by reference in their entirety to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated by reference in its entirety.

What is claimed is:

1. A balloon dilation catheter comprising:

a tubular member having a proximal end and a distal end;

an inflatable balloon disposed at the distal end of the tubular member;

a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon;

a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening in the tubular member and a second opening at the distal end of the tubular member; and

a slit-forming region disposed longitudinally in the tubular member and extending along at least a portion of the tubular member, the slit-forming region causing formation of a first slit as the guidewire is separated from the second lumen.

2. The balloon dilation catheter defined in claim 1, wherein the slit-forming region extends from the first opening to an area on the tubular member which is proximal to the inflatable balloon.

3. The balloon dilation catheter defined in claim 1, wherein the slit-forming region extends from the first opening to the second opening.

4. The balloon dilation catheter defined in claim 1, wherein the inflatable balloon comprises a second slit in substantial alignment with the slit-forming region.

5. The balloon dilation catheter defined in claim 4, wherein at least a portion of the second slit is reinforced.

6. The balloon dilation catheter defined in claim 1, further comprising a third lumen for receiving a stiffening member.

7. The balloon dilation catheter defined in claim 6, further comprising the stiffening member disposed in the third lumen.

8. The balloon dilation catheter defined in claim 6, wherein the third lumen at least partially encompasses the second lumen.

9. The balloon dilation catheter defined in claim 1, wherein the first lumen and the second lumen each comprise a passageway having a substantially circular cross-section disposed in a substantially solid tubular member.

10. The balloon dilation catheter defined in claim 1, wherein the slit-forming region extends along substantially the entire length of the tubular member.

11. The balloon dilation catheter defined in claim 1, wherein the slit-forming region extends along a portion of the length of the tubular member.

12. The balloon dilation catheter defined in claim 11, further comprising a third slit disposed in the tubular member.

13. The balloon dilation catheter defined in claim 12, wherein the third slit and the slit-forming region are in substantial longitudinal alignment.

14. The balloon dilation catheter defined in claim 12, wherein the third slit is disposed distally of the slit-forming region.

15. The balloon dilation catheter defined in claim 12, wherein the third slit is disposed proximally of the slit-forming region.

16. A catheterization kit comprising:

a guide catheter;

a guide wire; and

a balloon dilation catheter comprising: a tubular member having a proximal end and a distal end; an inflatable balloon disposed at the distal end of the tubular member; a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon; a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening in the tubular member and a second opening at the distal end of the tubular member; and a slit-forming region disposed longitudinally in the tubular member and extending along at least a portion of the tubular member, the slit-forming region causing formation of a first slit as the guidewire is separated from the second lumen.

17. The catheterization kit defined in claim 16, wherein the slit-forming region extends from the first opening to an area on the tubular member which is proximal to the inflatable balloon.

18. The catheterization kit defined in claim 16, wherein the slit-forming region extends from the first opening to the second opening.

19. The catheterization kit defined in claim 16, wherein the inflatable balloon comprises a second slit in substantial alignment with the slit-forming region.

20. The catheterization kit defined in claim 19, wherein at least a portion of the second slit is reinforced.

21. The catheterization kit defined in claim 16, wherein the balloon dilation catheter further comprises a third lumen for receiving a stiffening member.

22. The catheterization kit defined in claim 21, further comprising the stiffening member disposed in the third lumen.

23. The catheterization kit defined in claim 21, wherein the third lumen at least partially encompasses the second lumen.

24. The catheterization kit defined in claim 16, wherein the first lumen and the second lumen each comprise a passageway having a substantially circular cross-section disposed in a substantially solid tubular member.

25. The catheterization kit defined in claim 16, wherein the slit-forming region extends along substantially the entire length of the tubular member.

26. The catheterization kit defined in claim 16, wherein the slit-forming region extends along a portion of the length of the tubular member.

27. The catheterization kit defined in claim 26, further comprising a third slit disposed in the tubular member.

28. The catheterization kit defined in claim 27, wherein the third slit and the slit-forming region are in substantial longitudinal alignment.

29. The catheterization kit defined in claim 27, wherein the third slit is disposed distally of the slit-forming region.

30. The catheterization kit defined in claim 27, wherein the third slit is disposed proximally of the slit-forming region.

31. A stent-mounted balloon catheter comprising:

a tubular member having a proximal end and a distal end;

an inflatable balloon disposed at the distal end of the tubular member;

a stent mounted on the inflatable balloon;

a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon;

a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening in the tubular member and a second opening at the distal end of the tubular member; and

a slit-forming region disposed longitudinally in the tubular member and extending along at least a portion of the tubular member, the slit-forming region causing formation of a first slit as the guidewire is separated from the second lumen.

32. The balloon catheter defined in claim 31, wherein the slit-forming region extends from the first opening to an area on the tubular member which is proximal to the inflatable balloon.

33. The balloon catheter defined in claim 31, wherein the slit-forming region extends from the first opening to the second opening.

34. The balloon catheter defined in claim 31, wherein the inflatable balloon comprises a second slit in substantial alignment with the slit-forming region.

35. The balloon catheter defined in claim 34, wherein at least a portion of the second slit is reinforced.

36. The balloon catheter defined in claim 31, further comprising a third lumen for receiving a stiffening member.

37. The balloon catheter defined in claim 36, further comprising the stiffening member disposed in the third lumen.

38. The balloon catheter defined in claim 36, wherein the third lumen at least partially encompasses the second lumen.

39. The balloon catheter defined in claim 31, wherein the first lumen and the second lumen each comprise a passageway having a substantially circular cross-section disposed in a substantially solid tubular member.

40. The balloon catheter defined in claim 31, wherein the slit-forming region extends along substantially the entire length of the tubular member.

41. The balloon catheter defined in claim 31, wherein the slit-forming region extends along a portion of the length of the tubular member.

42. The balloon catheter defined in claim 41, further comprising a third slit disposed in the tubular member.

43. The balloon catheter defined in claim 42, wherein the third slit and the slit-forming region are in substantial longitudinal alignment.

44. The balloon catheter defined in claim 42, wherein the third slit is disposed distally of the slit-forming region.

45. The balloon catheter defined in claim 42, wherein the third slit is disposed proximally of the slit-forming region.

ABSTRACT OF THE DISCLOSURE

A balloon dilation catheter comprising: a tubular member having a proximal end and a distal end and an inflatable balloon disposed at the distal end of the tubular member. The tubular member comprises a first lumen disposed in communication with an interior of the inflatable balloon and a second lumen for receiving a guidewire substantially along the entire length of the tubular member. The second lumen has a first opening in the tubular member and a second opening at the distal end of the tubular member. A slit-forming region is disposed longitudinally along at least a portion of the tubular member. The slit-forming region causes formation of a first slit upon separation of the guidewire from the second lumen. The subject balloon dilation catheter provides improved rapid exchange advantages of either the catheter or the guidewire used in a catheterization technique.

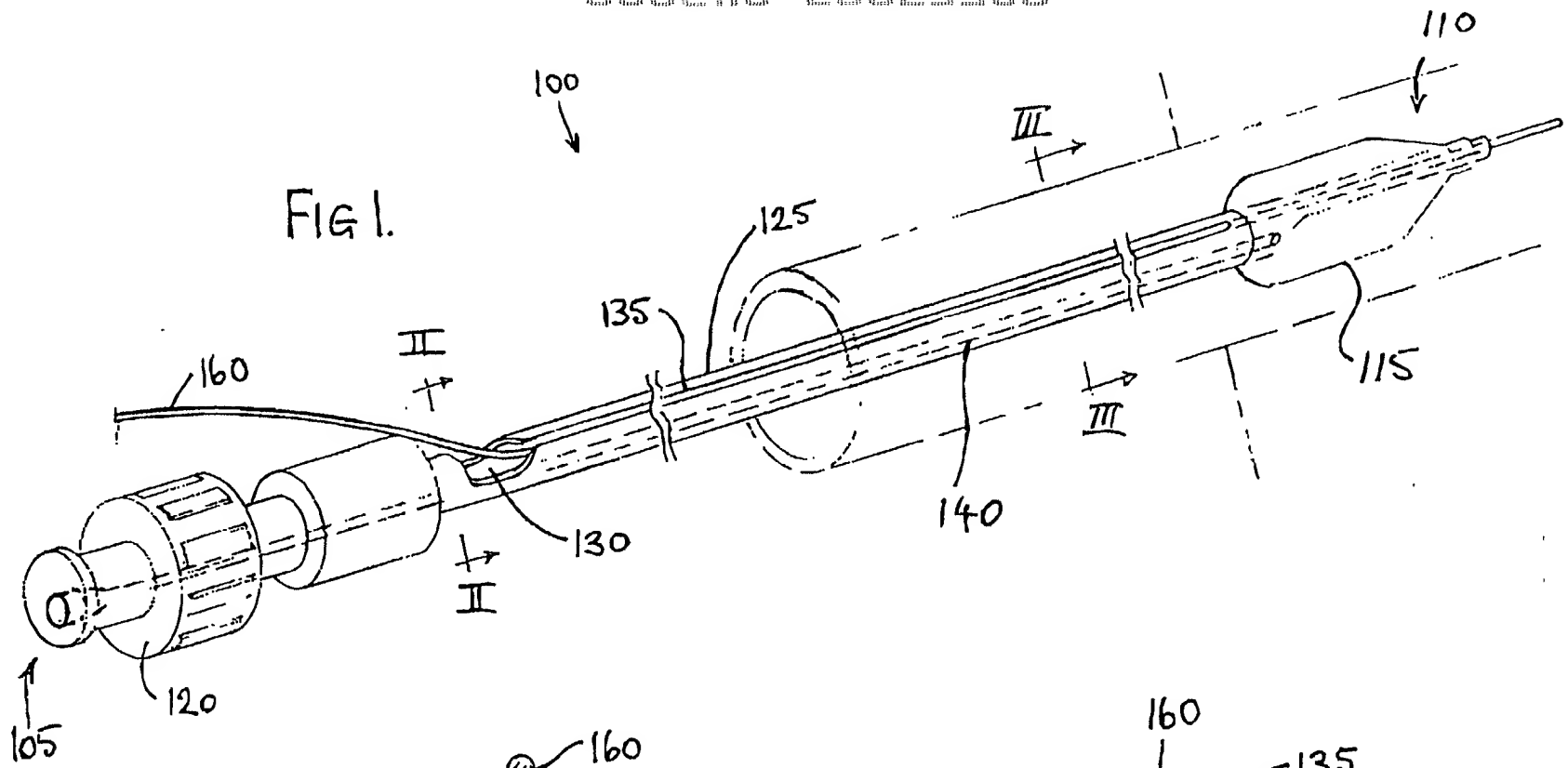
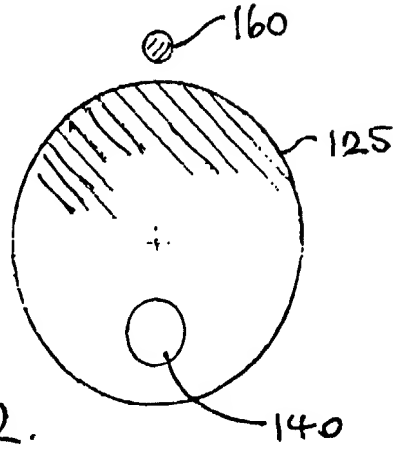


FIG 1.



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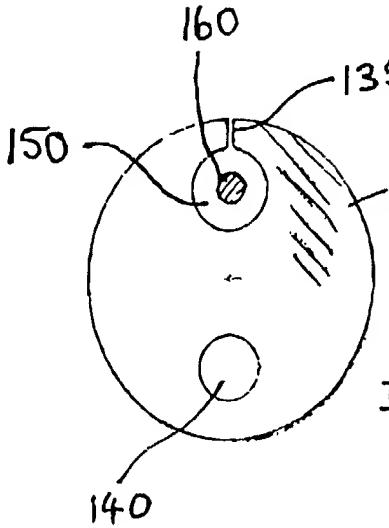
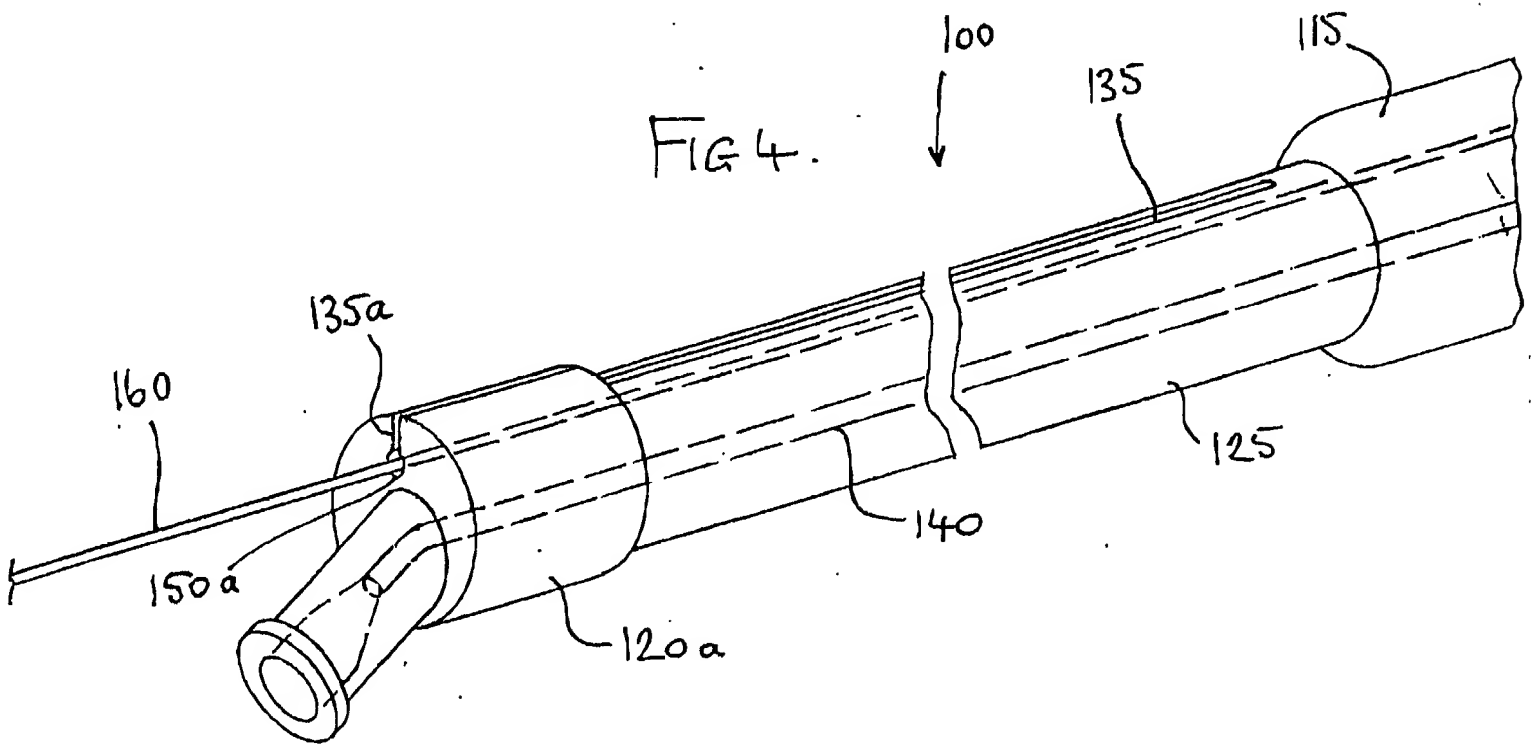


FIG 3.

FIG 4.



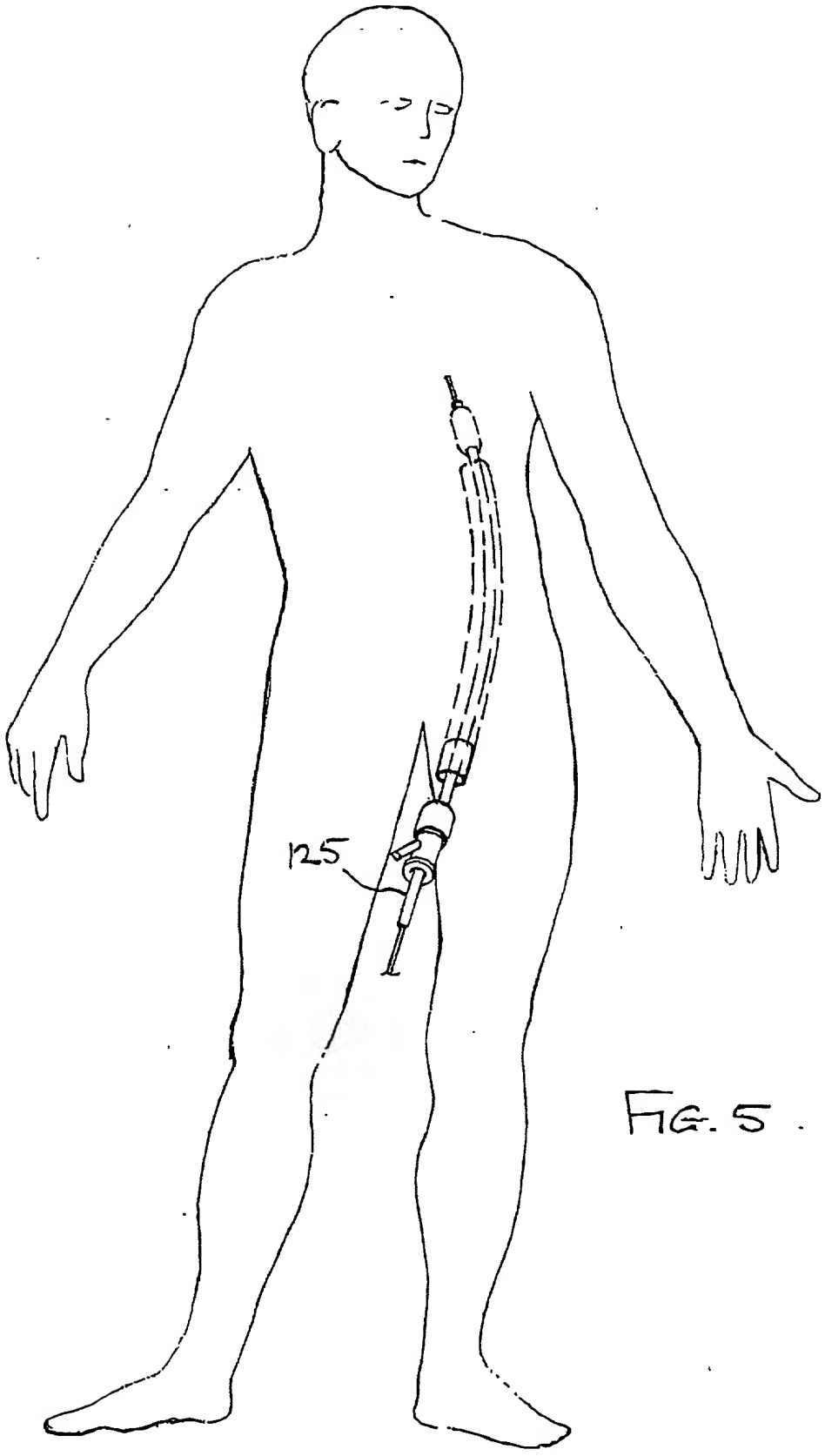
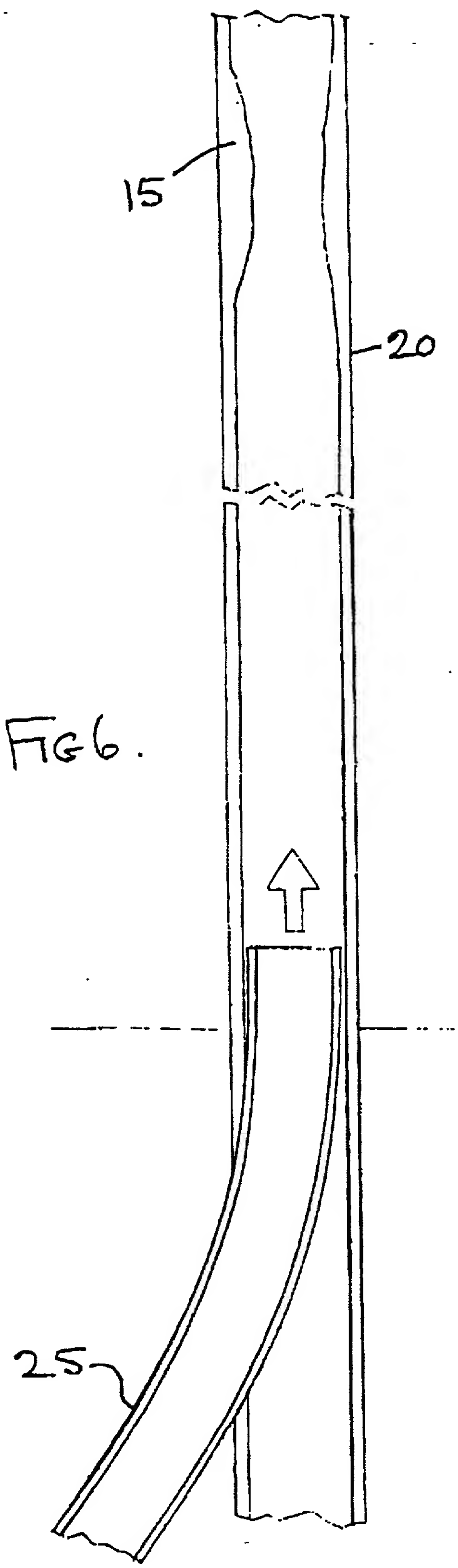


FIG. 5



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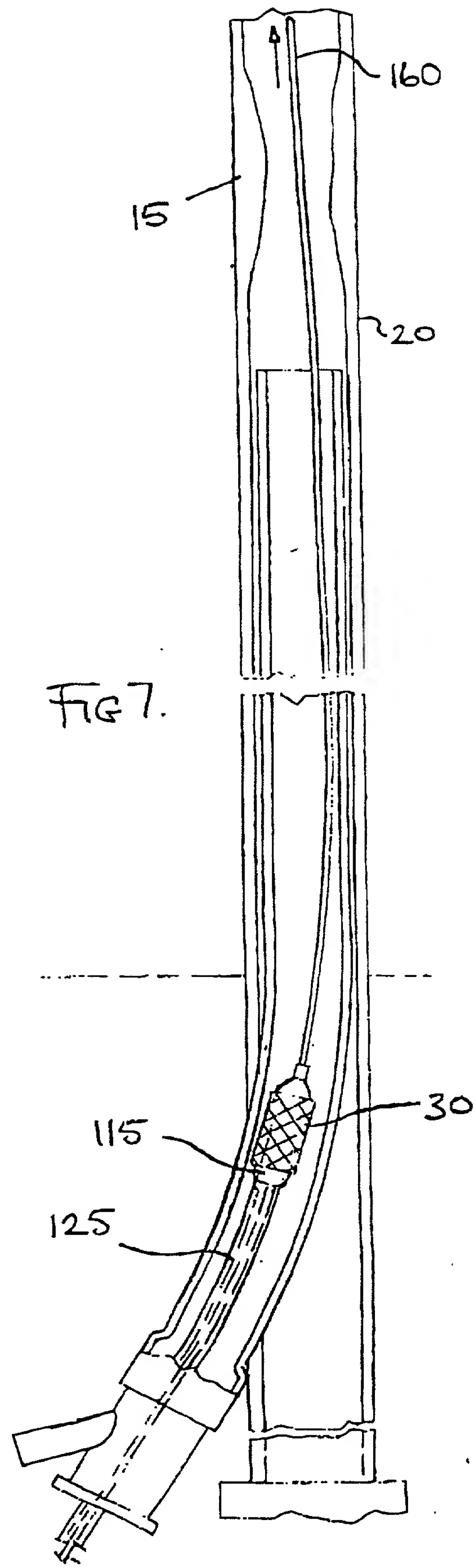

FIG 7.

C.

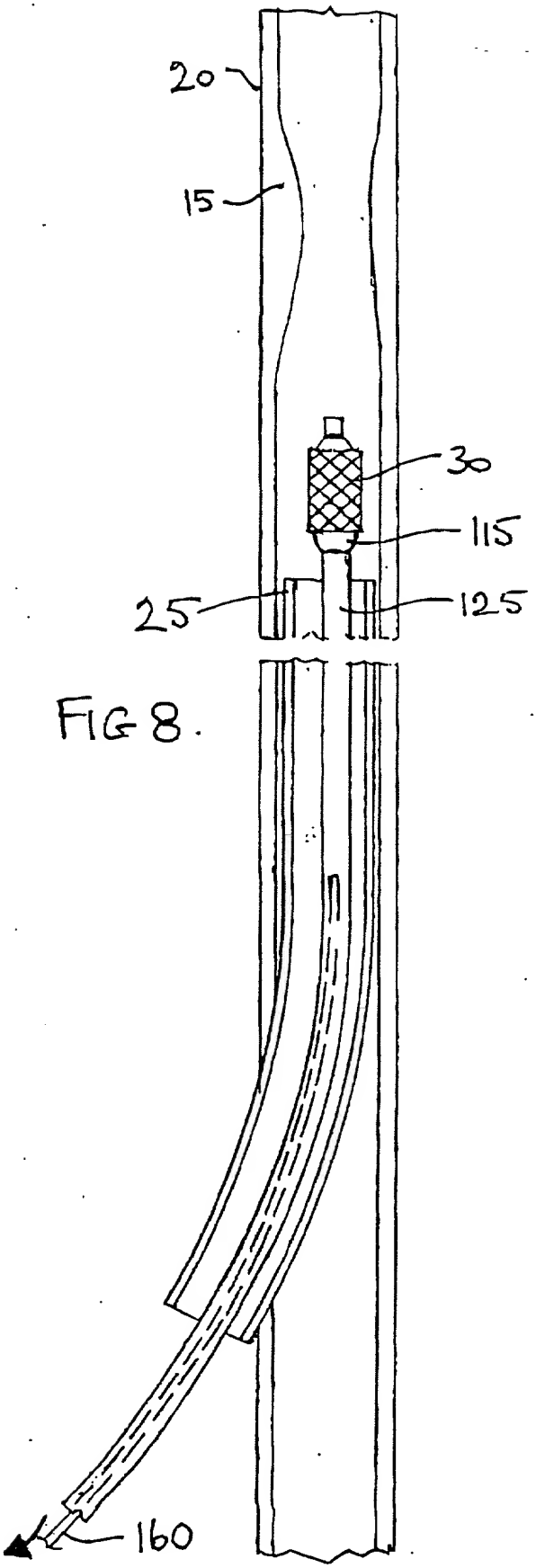

FIG 8.

D.

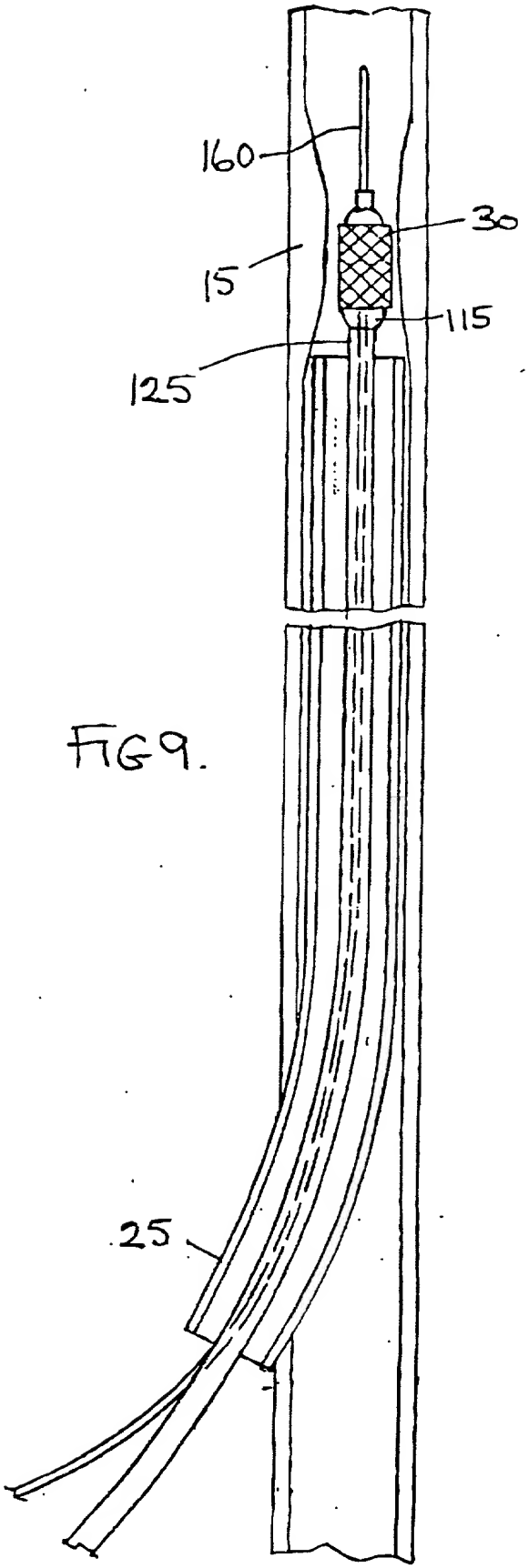

FIG 9.

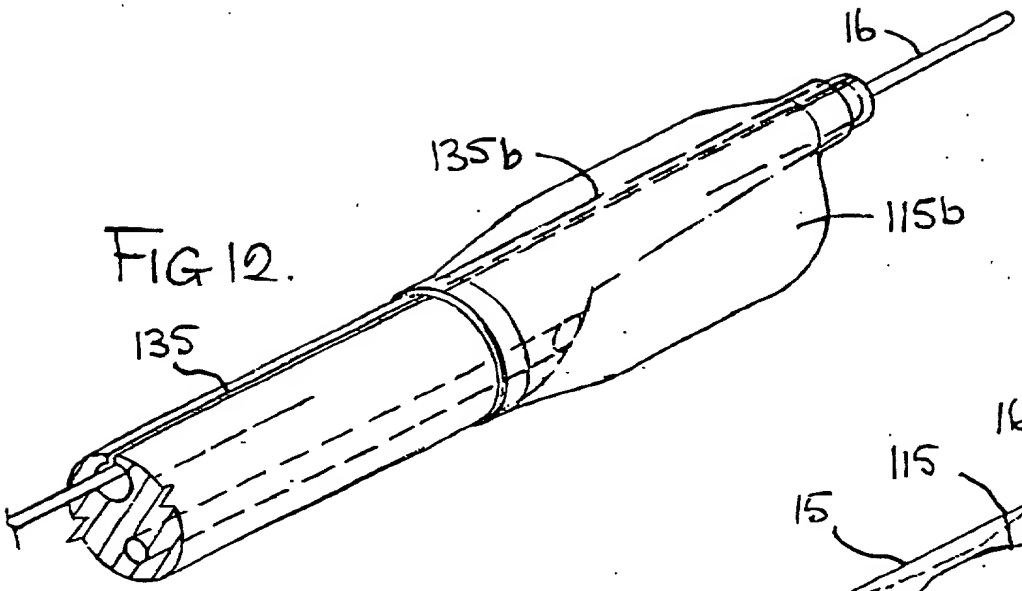

FIG 12.

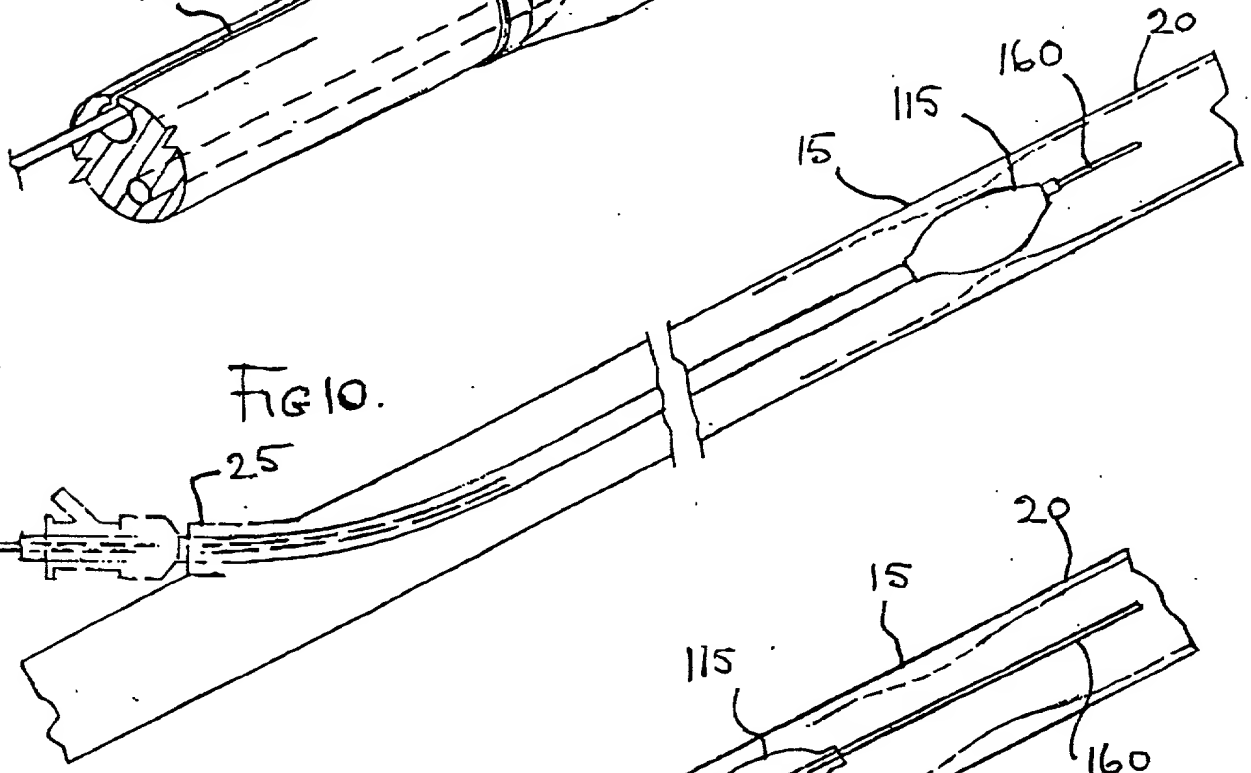

FIG 10.

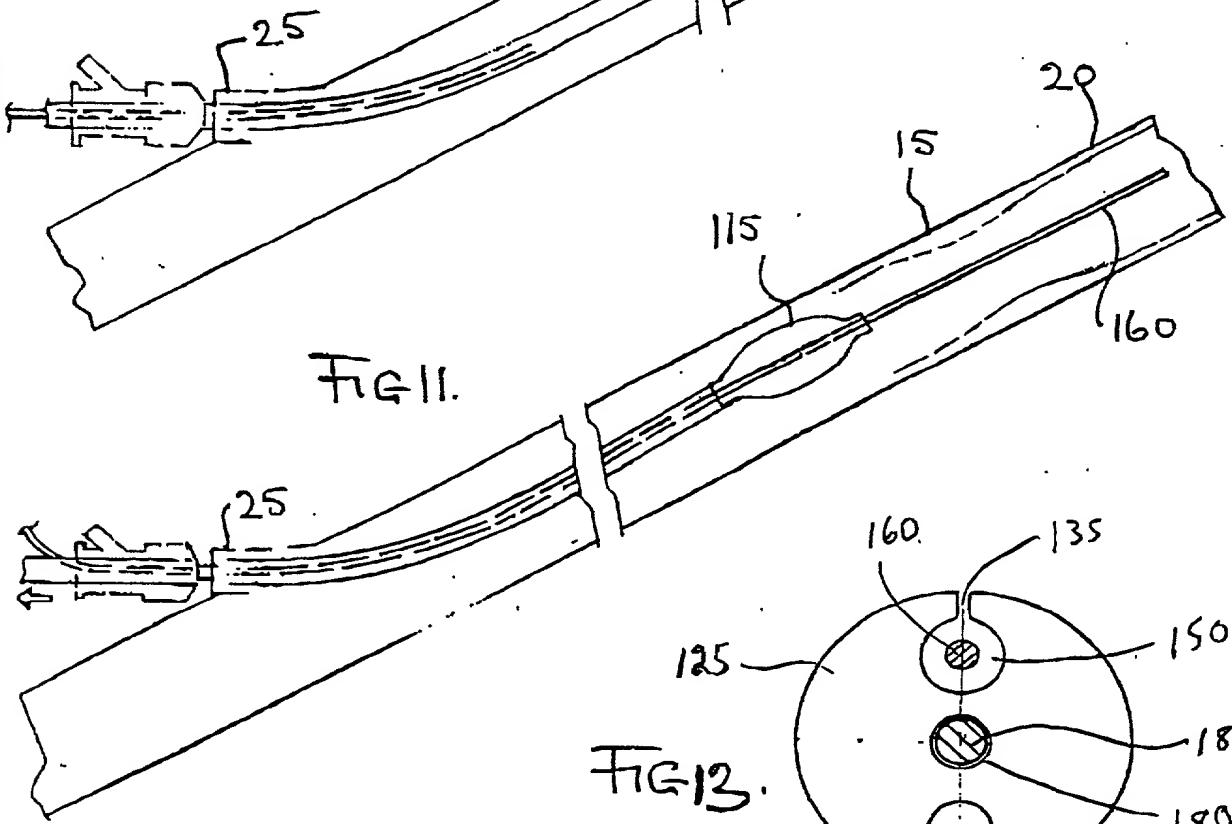

FIG 11.

FIG 13.

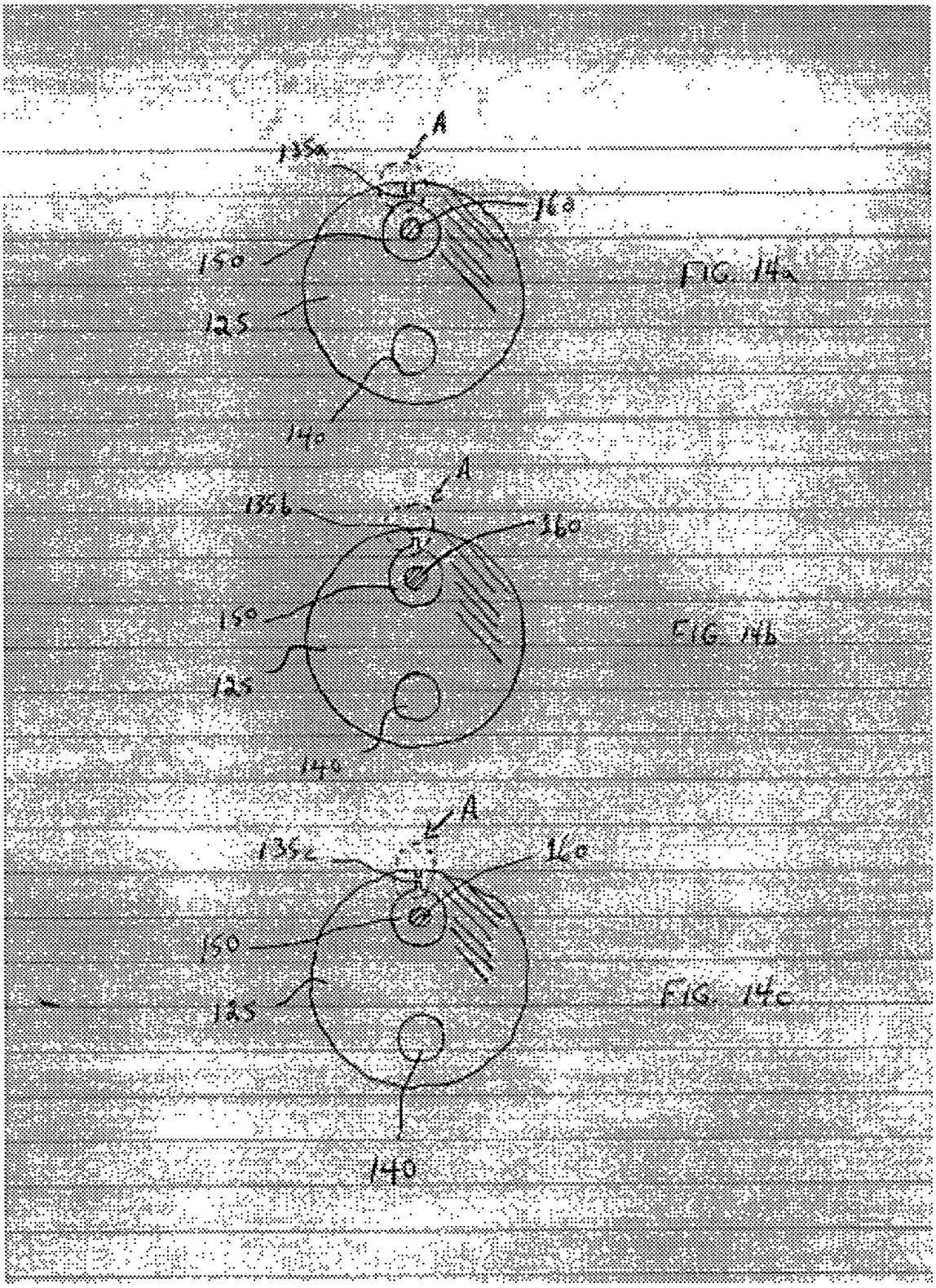

FIG. 14a

FIG. 14b

FIG. 14c

COMBINED DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION
(Page 1)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled STENT DELIVERY SYSTEM AND METHOD OF USE, the specification of which [X] is attached hereto [ ] was filed on _____ as United States Application No. or PCT International Application No. _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b), of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designates at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed:

Country	Application No.	Filed (Day/Mo./Yr.)	(Yes/No) Priority Claimed

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application No.	Filed (Day/Mo./Yr.)

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentabililty as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Application No.	Filed (Day/Mo./Yr.)	Status (Patented, Pending, Abandoned)
09/501,981	February 11, 2000	Pending

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION
(Page 2)

I hereby appoint the practitioners associated with the firm and Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and direct that all correspondence be addressed to the address associated with that Customer Number:

FITZPATRICK, CELLA, HARPER & SCINTO
Customer Number: 05514

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Sole or First Inventor DONALD R. RICCI

Inventor's signature

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